Transcutan

T-port® Enteral Access System

CE 0197

[T-port® Enteral Implant Kit Basic UDI-DI: 07350115720 13QT] [T-port® Enteral Replacement Kit Basic UDI-DI: 07350115720 14QV]
[T-port® Tools Kit Basic UDI-DI: 07350115720 15QX]

Instructions for Use

T-port® Enteral Implant Kit

T-port® Enteral Replacement Kit

T-port® Tools Kit

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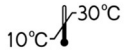
⚠ Latest valid product information is available on the Transcutan website: www.transcutan.com/t-port

Symbol definition

The following symbols may appear on the device packaging or in these Instructions for Use (IFU)

Symbol	Definition
	Caution
	Manufacturer
	Production batch code
	Reference number / Article number
	Use-by date, stated as year and month according to the format YYYY-MM
	Do not reuse
	Do not resterilise
	Sterilised using ethylene oxide
	Consult Instructions for Use
	Keep dry
	Do not use if packaging is damaged
	Store at temperatures between 10 and 30°C
	Medical device
	Unique device identifier
	MR conditional
	Contains hazardous substances
	Health care centre or doctor
	Date of medical procedure
	Patient identification
	Patient information website
CE	Indication of conformity with essential health and safety requirements set out in European Directives

Transcutan T-port® Enteral Access System User Manual

1. DESCRIPTION

The T-port® Enteral Access System offers safe, aesthetic and well-functioning transcutaneous, gastro-intestinal access. The system consists of a port made of medical grade titanium and stainless steel, and a polyurethane enteral catheter. The design allows for an easy exchange of catheter. The top of the port is fitted with a male ENFit (or alternatively a male Luer-Lock) connector, allowing easy connection to external devices. The system should be positioned by skilled, and for the purpose well-trained, physicians (e.g. an interventional radiologist). It is supplied as a sterile device, and is intended for single patient and single use only.

2. INTENDED USE

The T-port® Enteral Access System is indicated when patient therapy requires repeated and/or long-term access to the gastrointestinal tract. The system can be used for enteral delivery of medications, nutritional supplementation and fluids.

3. CONTRAINDICATIONS

- Patients with thin and fragile skin (e.g. after long-term corticosteroid therapy, cachexia)
- Liver disease with portal hypertension
- Ascites
- Medication and conditions leading to coagulation disorders
- Inflammatory small intestinal disease (Chron's Disease)
- Ongoing local or systemic infection
- Active gastric ulcer/inflammation
- Patients unable to undergo, or who are not compliant with, the necessary postoperative and long-term care

4. WARNINGS AND PRECAUTIONS

General

- Read the User Manual carefully. Failure to properly follow the instructions, warnings and precautions may lead to serious consequences for, or injury to, the patient.
- The T-port® Enteral Access System should only be used by physicians and teams trained in T-port® implantation procedure. Specific training expectations are described in section 10.
- The T-port® Enteral Access System is supplied STERILE. Do not use if the sterile barrier is damaged. If damage is found, call your Transcutan representative.
- The T-port® Enteral Access System is intended for single patient and single use only. Do not reuse, reprocess or resterilise the device. Reuse, reprocessing or resterilisation may compromise the structural integrity and/or create a risk of contamination of the device, which, in turn may lead to injury to the patient.
- The T-port® Enteral Access System must be used with the supplied Enteral Access Catheter.
- Do not use the T-port® Enteral Access System beyond the expiration date printed on the packaging.
- The T-port® Enteral Access System consists of chemically stable materials. Compatibility with all possible medications cannot, however, be guaranteed.
- The stainless-steel parts of the device are manufactured with alloys containing a CMR substance i.e. Cobalt (CAS no.: 7440-48-4) in concentrations above 0.1% w/w. The residual risk for the patient or user is found to be acceptable, and no precautionary measures are needed.

Patient selection, treatment and follow-up

- The T-port® Enteral Access System is not recommended for patients with known sensitivities or allergies to titanium, stainless steel, polyurethane or silicone.
- Patients with a systemic infection are at increased risk of stoma infection.
- Patients with signs of local infection near the site of implantation are at increased risk of stoma infection.
- Avoid placing the T-port® in an area with significant scar tissue.
- Avoid placing the T-port® in areas with substantial movements.
- The T-port® Enteral Access System is not recommended in patients who are unable to undergo, or who will not be compliant with, the necessary postoperative and long-term care.
- In patients with thin and fragile skin (e.g. after long-term corticosteroid therapy, cachexia), there is an increased risk that the edge of the subcutaneously placed flange may pressurise the skin and cause necrosis of the overlying skin.
- Avoid placing the T-port® in a skin-fold. Check the implantation site with the patient both in supine and sitting positions.
- Avoid placing the T-port® close to the costal arch to avoid the risk of causing pain.
- Any skin disease at the site of implantation may increase the risk of stoma infection.
- An extremely oblique implantation position of the port should be avoided. With a T-port® implanted in a very oblique position, there is a risk that the edge of the subcutaneously placed flange may pressurise the skin and cause necrosis of the overlying skin.

5. (UNDESIRABLE EFFECTS) ADVERSE EVENTS

Long-term transcutaneous access devices should be implanted by physicians familiar with catheter introductions, checked regularly by caregiving staff, and regularly cleaned by the patient. Complications that may be associated with the use of transcutaneous access products include, but are not limited to, the following:

Adverse Event	Possible Cause
Slight skin irritation and debris formation with risk for staining of clothes	Leakage from the T-port® (Top inadequately tightened or tightened too hard causing Top to break, wrong catheter, catheter used without Catheter Cone), poor hygiene, forgetting to cap the ENFit or Luer-Lock port when not used, deep implantation causing ENFit or Luer-Lock to rub against the skin
Pocket inflammation leading to irritation, secretion and proud flesh formation	Continuous micro-movement and leakage from the T-port® Base in the pocket
Pocket infection	Poor hygiene, poor sterility condition during implantation, implantation in a skin-fold, T-port® not sterile at delivery, catheter replacement under poor hygienic conditions, re-sterilisation and re-use of T-port® parts, uncooperative patient
Pocket wound, pocket bleeding	Excessive force on externally connected device when not using a weak-link connection tube
Pain around pocket	Inflammation, infection, impact on or disturbance of T-port®, excessive force on externally connected device when not using a weak-link connection tube
Skin penetration by the subcutaneous flange	Oblique implantation, chronic pocket inflammation, severe infection, skin disease, wrong implant site, thin skin
Explantation of the system	Non-treatable pocket infection, chronic pocket inflammation, severe ulcer caused by catheter, oblique implantation, chronic pain
Irritation, ulcer and possible penetration of the intestinal wall by the catheter	Using wrong catheter, catheter stiffening due to incompatible substance delivered over a long period of time, intestinal disease
Peritonitis	Dislocation of catheter to the peritoneum, poor fistula between pocket and the stomach allowing leakage of gastric juice into the peritoneum, leakage from the T-port® into the peritoneum
Systemic infection with sepsis	Severe pocket infection due to non-sterile condition at implantation, poor hygiene, poor condition of the patient, uncooperative patient
Wrong dose of medication or supplied nutrition	Leakage from the T-port®, kink in the catheter, clotting of the catheter
Wrong delivery location of medication or supplied nutrition	Dislocation of catheter, rupture of catheter, breakage of catheter
Leaving a broken section of the catheter in the stomach or the small intestine	Use of the catheter for too long time without exchange, use of wrong catheter, very active patient causing much strain on the catheter, catheter becoming fragile or weakened due to incompatible substance delivered over a long period of time

6. SUMMARY OF CLINICAL STUDIES

A soft-tissue anchored percutaneous device for long-term intracorporeal access was first developed by Lundgren et al. in 1989 (1). Its first intended use was for insulin delivery to the peritoneum. It was shown that the device was well-incorporated and fixated in the subcutaneous tissue, and that an epidermal seal was obtained. The device was further developed and connected to a catheter that could be exchanged. In 2001, a clinical study of 11 patients with malignant obstruction of the bile ducts was performed (2). The study was approved by the research ethics committee of Uppsala. It was shown that the device was well-tolerated by all the patients, and healed in uneventfully without any major adverse advents. The mean implantation time was 9 months. A cyclic variation in the colour of the skin surface immediately adjacent to the implant was also noted in all patients, deviating from that of the surrounding tissue to a slight or moderate redness, sometimes with slight oedema. No serous exudation or pus formation was observed. This is a type of reaction seen around most titanium implants (3)(4)(5)(6)(7)(8)(9).

Shortly thereafter, a collaboration was initiated with Neopharma AB concerning drug delivery access in cases of Parkinson's disease. Neopharma was developing a new formulation of L-dopa (DUODOPA®) – a gel that was to be delivered in the small intestine of patients with advanced Parkinson's disease, where oral treatment is no longer effective (10)(11)(12)(13). They were using gastrostomy (PEG and J-tube) to create an artificial external opening in the stomach for nutritional support or gastrointestinal decompression, but were in need of a better access technology. The major drawbacks of the PEG system were complications related to the tube (kinking, blockage) and connectors (leakages), together with leakage and infection around the stoma (14)(15)(16)(17)(18)(19)(20)(21)(22)(23). In addition, patients have also been reluctant to try DUODOPA®, due to the discomfort and unattractiveness of the tube protruding from the abdomen.

A case series study approved by the research ethics committee of Uppsala was performed (24). The first T-port® replacing the need for normal gastrostomy (the T-port® Enteral Access System) was inserted in January 2003. A total of 15 patients had a T-port® implanted for a combined total of 34.5 years (mean 2.3 years/patient, with a maximum duration of 4.9 years). All percutaneous procedures were performed under local anaesthesia, without any major discomfort for the patients. The patients have been followed and all events related to the procedure have been carefully registered using a specially designed protocol. The patients tolerated the procedure and the device well. There was no problem with blockage, kinking or dislocation of the tube, or leakage of gastric juice. The same observation with cyclic variation in the colour of the skin surface immediately adjacent to the implant was also noted in all patients, deviating from that of the surrounding tissue to a slight or moderate redness. Slight oedema with hypergranulation tissue was sometimes also encountered. Two major problems were encountered with penetration of the skin of the flange and leakage of DUODOPA® at the connection site. This led to a redesign of the port with a vault flange, and a more secure connection between the dome and the T-port® base (generation III T-port®), which substantially reduced these problems. All explantations of the T-port® were performed under local anaesthesia, and the wounds in the explanted area healed uneventfully.

A case series study approved by the research ethics committee at UMCG, Groningen, Netherlands was conducted between September 2007 and December 2008 (25). The patients were carefully monitored and the data was registered in a specially designed protocol over the course of 6 months. A total of 15 patients (8 former PEG and 7 non-PEG) with advanced Parkinson's disease were included and had T-port® generation III implanted. There were no technical problems with the implantation, and the wounds healed uneventfully. There were no major adverse events, and seven of the eight former PEG patients rated the T-port® system as good to very good. The total lack of obstructions, kinking, retractions or leakage was an important improvement compared to the former PEG systems. Within the first 6 months, therefore, the tolerability of the T-port® was considered to be 100%.

A total of 24 patients have had an implanted generation III T-port® and have been continuously monitored, in both Uppsala (9 patients) and Groningen (15 patients), following the designed protocol (26). The combined total implantation time was 83.6 years, with an average time/patient of 3.6 years (1.1-5.2 years). Ten T-port®s have been explanted under local anaesthesia, without any wound healing problems. Two of these were explanted after 1 year, 2 after 2 years, 1 after 3.5 years, 3 after 4 years and 2 after 5 years. The reason for explantation was loosening and migration of the port in 7 cases, infection in 2 cases, and the patient's own request in 1 case. All 10 T-port®s could be explanted under local anaesthesia, without any wound healing problems. Two patients with T-port® have deceased, for reasons not related to the T-port®. Twelve patients still have a working T-port®, with a mean implantation time of 3.5 years (range 2-4.5 years). The long-term results also demonstrate a total lack of obstructions, kinking or retractions of the tubes. The same observation with cyclic variation in the colour of the skin surface immediately adjacent to the implant was also noted in all patients, deviating from that of the surrounding tissue to a slight or moderate redness, and sometimes with slight oedema with more or less hypergranulation tissue. Most patients were somewhat bothered by more or less secretion of a brownish debris material around the port. This local inflammatory reaction could, in most cases, be controlled with local cleaning, cortisone ointment and lapis of the hypergranulation tissue. If this could not be controlled over time, it inevitably led to the loosening and rejection of the port. No leakage of DUODOPA® or gastric juice was observed.

In a post-market clinical follow-up study, 39 patients (36 with Parkinson's disease and 3 due to nutrition) had the T-port® implanted and were monitored for 12 months. A total of 9 T-port®s were explanted during this time. Five of these could be considered as procedure-related, 2 were due to anchoring problems, 1 was due to infection caused by placing the T-port® close to the DBS wire, 1 was due to a poorly fixated ground plate with stitches, and 1 was due to pain caused by the T-port® being placed too close to the costal arch. The other 4 explantations were due to poor hygiene, 1 of which was due to infection that resulted in ground plate perforation, 1 was due to severe pull and trauma, and 2 were due to patient request without problems with T-port®.
Of these 9 explantations, 3 were exchanged to a new T-port® on the same occasion; in 2 of these cases, the T-port® was still working fine (> 2 years), and 1 case there was a new perforation and exchanged to PEG. Three of the 9 were exchanged to PEG, and 2 were exchanged to DBS. One was removed following the patient's request, and this was not replaced by either a new T-port® or PEG.
The wound healing period after all explantation was uneventful in all cases. The explantation and exchange to a new T-port® was performed on 6 occasions – 3 during the 12 month study period, and 3 after the 12 month study period. These procedures were performed under local anaesthetic and with antibiotic protection, and the wound healing was uneventful in all cases.

Assessment of risks and benefits

The risks of serious adverse events (SADE) are mainly related to the implantation procedure, and are the same as those identified for comparable procedures with PEG and RIG. The ADEs during the follow-up period were mainly pocket infections/inflammations secondary to anchor problems, poor fixation of ground plates, trauma and poor hygienic care. The explantations and implantations of new ports or replacement with RIG-J were performed under local anaesthesia with low risk. No tubes had to be replaced due to blockage or dislocations, which represent a major problem found with PEG-J devices.
The risk management related to the T-port® has been conducted in accordance with ISO 14971. The severity and frequency of all identified ADEs has been assessed. Based on this assessment, the benefit of the use of the T-port® is considered to exceed the risk.

The main risk associated with the device relates to the interface between the penetrating part of the T-port® and the skin edge, where a small sinus or pocket naturally appears, and where dead tissue debris (a brownish wax-like material) accumulates. This sinus could be a possible locus for the development of superficial infection/inflammation with slight secretion, debris and sometimes hypergranulation tissue. This risk can most likely be reduced by a strictly optimised implantation technique, the choice of optimal sites for implantation, and strict hygiene routines (27).

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7. DEVICE DESCRIPTION

The T-port® Enteral Access System is made up of the following components:

- T-port® Base (1)
- T-port® Top (2) with either Luer-Lock (2/L) or ENFit (2/E)
- T-port® Catheter Cone (3)
- T-port® Enteral Catheter with Catheter Cone Mounted (4)
- T-port® Catheter Holder (5)
- T-port® Base Holder (6)
- T-port® Top Wrench (7)

The Base, the Top, the Cone, and the Enteral Catheter (1-4) form the actual access, while the remaining items are tools that are needed during implant or catheter replacement (5-7).

1

The T-port® Base (1) is made up of a ring-shaped flange that is placed subcutaneously and a tower that penetrates the skin. The flange contains two rows of circumferential perforations, allowing ingrowth of connective soft tissue that will safely anchor the Base (1). At the centre, there is conically shaped pass-through, allowing insertion of the Enteral Catheter.

Material: non-alloyed, medical grade 2 and biocompatible titanium

2

2/E

The T-port® Top (2) is made up of a male Luer-Lock (2/L) or, alternatively, a male ENFit (2/E)) connector welded to a Dome. In the Dome, a freely rotating threaded "Centre piece" fits into the pass-through of the Base (1). The "Centre piece" is hollow and forms a connection from the male connector to the Enteral Catheter (4) fitted in the Base (1). At the top level of the Dome, the "Centre piece" is formed into a hex socket, allowing tightening of the T-port® with the Top Wrench (7). As the "Centre piece" rotates freely inside the Dome, the tightening can be performed without rotating the Luer-Lock connector. When the Top is fully screwed down in the Base (1), the "Centre piece" of the Top presses the Enteral Catheter fitted with the Catheter Cone (4) against the conically shaped pass-through in the Base (1), forming a tight seal. Sealing rings on the "Centre piece" further ensure tightness. The flat plane of the Dome contains three sharp points that will grab into the tower of the Base when the Dome is screwed into the Base (1), thereby eliminating the problem of gradual unscrewing over time. To assure the integrity of the sharp

points, the Top should always be changed in conjunction with a catheter exchange.
Material: Stainless steel and medical grade silicone.

3

The Catheter Cone (3) is a 10 Fr cone with a central lumen, containing push-on hose barbs for a tight fit into the end of the Enteral Catheter (4), which allows the catheter to be tightly affixed against the conically shaped pass-through in the centre of the Base (1).
Material: Stainless steel.

4

The T-port® Enteral Catheter (4) is a single lumen radiopaque 10 Fr pigtail catheter with a working length (with the pigtail) of 550 mm. The diameter of the pigtail, which contains 4 oval holes, is around 21 mm. The catheter has a forward hole to allow for passage of a 0.97 mm (0.038 inches) guidewire. At the proximal end of the Enteral Catheter, the Catheter Cone (3) is pre-mounted. The volume of a catheter is 2.2 ml.
Material: medical grade biocompatible polyurethane and stainless steel Catheter Cone

5

The Catheter Holder (5) is used when inserting or retracting the Enteral Catheter (4) into the Base (1). It contains a threaded tip, fitting the inside threads of the Catheter Cone (3). A central lumen allows passage of a 0.97 mm (0.038 inches) guidewire.
Material: Stainless steel

6

The Base Holder (6) is used to affix the Base (1) during screwing or unscrewing the Top (2). It fits into two parallel chamfers in the tower of the Base (1).
Material: Stainless steel

7

The Top Wrench (7) is used to screw/unscrew the Top (2) into/from the Base (1) in conjunction with implantation and catheter exchange.
Material: Stainless steel

8. WHAT IS SUPPLIED

The T-port® Enteral Access System is available in five kits:

T-port® Enteral Implant Kit with Luer	Art. Number: 1010-1/L
T-port® Enteral Implant Kit with ENFit	Art. Number: 1010-1/E
T-port® Enteral Replacement Kit with Luer	Art. Number: 1020-1/L
T-port® Enteral Replacement Kit with ENFit	Art. Number: 1020-1/E
T-port® Enteral Tools Kit	Art. Number: 1030-1

KITS

A cardboard box containing STERILE double peel open pouches (PACKS), according to:

The T-port® Enteral Implant Kit with Luer

Items needed for a new implant:

- T-port® Base Pack
- T-port® Top Pack - Luer
- T-port® Tools Pack
- T-port® Enteral Catheter Pack

The T-port® Enteral Implant Kit with ENFit

Items needed for a new implant:

- T-port® Base Pack
- T-port® Top Pack - ENFit
- T-port® Tools Pack
- T-port® Enteral Catheter Pack

The T-port® Enteral Replacement Kit with Luer

Items needed for a catheter replacement:

- T-port® Top Pack - Luer
- T-port® Tools Pack
- T-port® Enteral Catheter Pack

The T-port® Enteral Replacement Kit with ENFit

Items needed for a catheter replacement:

- T-port® Top Pack - ENFit
- T-port® Tools Pack
- T-port® Enteral Catheter Pack

T-port® Enteral Tools Kit

Separate set of instruments:

- T-port® Tools Pack

PACKS

STERILE double peel open pouches

T-port® Base Pack

- T-port® Base (1)

T-port® Top Pack - Luer

- T-port® Top - Luer (2/L)
- T-port® Catheter Cone (3)

T-port® Top Pack - ENFit

- T-port® Top - ENFit (2/E)
- T-port® Catheter Cone (3)

T-port® Tools Pack

- T-port® Catheter Holder (5)
- T-port® Base Holder (6)
- T-port® Top Wrench (7)

T-port® Enteral Catheter Pack

- T-port® Enteral Catheter with pre-mounted Catheter Cone (4)

9. DEVICE PARTICULARS

Shelf life
The expiration date is printed on the carton box label and outer pouch label of each pack in the format year- month (YYYY-MM). Do not use the items beyond the expiration date.

Special precautions for storage
Store the pack at room temperature, in a dry place.

Disposal
Packaging material: Dispose of as appropriate
Explanted items: Dispose of following standard solid biohazard waste procedures

Sterilisation
The packs have been sterilised in ethylene oxide.

Compatibility with external devices
The Luer-Lock version is compatible with external equipment with a female Luer-Lock connector.
The ENFit version is compatible with external equipment with a female ENFit connector.

Tightness
The T-port® Enteral Access System is completely watertight when properly tightened.

Proper tightening torque
Tightening the T-port® Top (2) to the level where the Top's lower surface comes close to the upper surface of the T-port® Base (1) is enough to create a tight seal. This occurs at a torque of around 0.8 Nm and with a gap of 0.5 mm. Additional torque will not improve the tightness.

Max. tightening torque
The T-port® Top should never be tightened more than 2 Nm.

Compatibility with delivered substances
The T-port® Enteral Access system is a tool for the repeated channelling of nutrition and/or medication into the intestinal system. Methods of administration (syringe, pump, gravitational force, etc.), concentrations, dose, flow rates and frequency of delivery will depend on the disease and will be determined by the treating physician. The same drug and enteral feeding formulation and methods for administration as used for regular PEG-J and RIG-J systems can be used with the T-port® Enteral Access system. The risk is the same with all jejunostomy accesses, and the majority of drugs do not have a specific formulation used for this process.
It is the responsibility of the treating physician to determine whether a specific substance or combination of products is contraindicated to be used with the materials in the T-port® Enteral Access System.

10. CLINICAL USE INFORMATION

The T-port Enteral Access System has been developed to be suitable for patients requiring repeated access to the gastrointestinal tract in order to provide enteral delivery of medication, nutritional supplementation and fluids.

The intended users are:

i) Clinical professionals (trained physicians) for the implantation;

ii) Caregiving staff that are trained in the use and maintenance of gastrointestinal access products;

iii) The end user, the patient.

Experience of the implanting physician
Clinical professionals (trained physicians) for the implantation should have received theoretical background information regarding the T-port® Enteral Access System, followed by a supervised implantation procedure. The training of the operator shall be performed by an experienced interventional radiologist who has been trained in the use of the T-port® Enteral Access System. The training includes: indications, contraindications, preoperative recommendations, product design, surgical tools and equipment needed, surgical implantation method and postoperative procedures (fasting, pain relief, removal of sutures).

Experience of caregiving staff
The caregiving staff should have received theoretical background information regarding the T-port® Enteral Access System. The training of the caregivers shall be performed by a registered nurse with experience in gastrointestinal infusion therapy. This training includes information concerning pre- and postoperative care, product design and practical use.

Inspection prior to use
Inspect the device and packaging to verify that no damage has occurred as a result of shipping. Do not use this device if any damage has occurred or if the sterilisation barrier has been damaged or broken. If any damage has occurred or if the sterilisation barrier has been damaged or broken, return the items to your Transcutan representative.

Materials recommended for implantation
These items are NOT included in the Transcutan T-port® Enteral Access System.

- Nasogastric tube and air pump for insufflation of air to the stomach
- Sterilised forceps, scissors, tweezers, knife and sterile gauze. Contact your sterilisation department and get a specially designed tray for this
- Local anaesthetic
- T-fastener
- Stiff guide wire with length of 150 cm and diameter of 0.035-0.038 inches.
- Glide wire with length of 150 cm and diameter of 0.035-0.038 inches
- Angiographic catheter
- Dilators 10 and 12 Fr
- Skin and subcutaneous sutures
- Saline
- Iodine contrast
- Extension Luer-Lock or ENFit tube between T-port® Top and external device
- Closure for Luer-Lock or ENFit (male)
- Female-female adapter, in order to be able to fit a Luer-Lock syringe or an ENFit syringe.

11. DIRECTIONS FOR USE

Patient preparation

- The doctor who plans to perform the implantation should check the implantation site. The T-port® Base (1) shall be placed in a comfortable area for the patient. Skin-folds at the implantation site should be avoided.
- Make sure that the patient is not receiving any anticoagulation therapy.
- Blood samples: Hb, serum creatinine, APTT, PK.
- Barium contrast can be given orally 8-12 hours before implantation in order to be able to visualise the colon using X-ray.
- Fasting 6 hours before implantation, but the patient can drink water up to 4 hours before the operation. Oral medication together with a small amount of water can be given up to the start of the operation.
- Wash the body.
- Place a nasogastric tube.
- Peripheral venous line with NaCl.

Premedication

Give premedication in line with institutional guidelines.

Intravenous antibiotics prophylaxis shall be given at the start of the implantation in line with institutional guidelines.

Implantation

- Check all parts of the T-port® Enteral Access System. The implantation should be aseptic with disinfection of the skin. The operator must use sterile clothes and instruments.
- In order to visualise the stomach, a suitable amount of air is insufflated through a nasogastric tube. The preferred selection of the puncture site is above the antrum of the stomach, avoiding skin-folds. Think also about the location of the patient's waist-lining. Avoid placing the T-port® too close to the costal arch. A local anaesthetic is injected into the puncture canal, and the stomach is punctured with the needle in the T-fastener set. Angle the needle slightly towards the pylorus, but avoid a puncture canal that is too oblique. The verification of the needle position within the stomach can be done with aspiration of air bubbles into the syringe and/or injection of iodine contrast. The T-fastener can then be safely inserted into the stomach. The T-fastener makes it possible to have control of the stomach wall during the procedure. A guide wire is placed through the needle into the stomach, and the needle is then taken out over the wire and replaced by a 4-5 Fr catheter. The string to the T-fastener is secured on the skin with forceps. In order to secure the stomach wall to the abdominal wall, 2 or 3 T-fasteners shall be placed at a distance of at least 2 cm from the T-port® implantation site. The pylorus is catheterised, and the tip of the catheter is placed beyond the ligament of Treitz.
- After infiltration of the skin around the puncture site with a local anaesthetic, a 2 cm long incision is made in the skin through the puncture site. Subcutaneous dissection is made to allow room for the perforated flange of the T-port® Base (1). Make sure that the dissection is deep enough and in the same plane as the skin surface to allow the T-port® Base flange to be covered with fatty tissue (at least 5 mm of subcutaneous tissue) and to avoid an oblique position. Ensure meticulous haemostasis to prevent haematoma. Check the dissection pocket using the T-port® Base (1). Put at least 3-4 sutures (preferably resorbable) into the muscle fascia, and affix them with forceps. They will later be used for the fixation of the T-port® Base.
- Place a stiff guide wire with the tip passing beyond the ligament of Treitz through the catheter, and then take the catheter out. Dilate the puncture track to 10-12 Fr using a dilator. Then place the T-port® Base (1) over the guide wire. Pull the Enteral Catheter with the pre-mounted metal T-port® Catheter Cone (4) over the wire and through the T-port® Base (1). The tip of the Enteral Catheter (4) should be beyond the ligament of Treitz. Plug the ENFit or the Luer-Lock with a suitable female cap. Close the port and affix

the catheter by screwing the T-port® Top (2) onto the T-port® Base using the T-port® Top Wrench (7) and the T-port® Base Holder (6). The direction of the ENFit or Luer-Lock can be individually chosen. Position the ENFit or Luer-Lock connector in the most optimal direction for the patient. Tightening the T-port® Top (2) to the level where the Top's lower surface comes close to the upper surface of the T-port® Base (1) is enough to create a tight seal. This occurs at a torque of around 0.8 Nm and with a gap of 0.5 mm. Additional torque will not improve the tightness.

- Place the fascia sutures through the perforated flange of the T-port® Base (1), which is then to be placed in the subcutaneous pocket. Cut the T-fastener string that passes through the wound and next to the catheter. Knot the fascia sutures and make sure that the T-port® Base is well affixed in a good position. Flush the wound carefully with saline solution. Then ensure that the stomach wall is in contact with the abdominal wall, and that there is no bending force on the tube. Tighten the T-fastener lines with a gentle tension, to avoid space between the stomach and the abdominal wall. Suture the skin around the tower, and ensure that there is no gap between the skin edge and the tower.
- Connect a suitable connection tube to the ENFit or Luer-Lock on the T-port® Top (2). Check for leakage and the position of the catheter by flushing the system with contrast media. Apply a bandage with slight compression over the wound, in order to minimise the risk of post-procedure bleeding. The bandage and the connection tube must be affixed with suitable skin-friendly tape in such a way as to prevent the port from leaning in any direction and to prevent any rotation force that could affect the port during the healing period.

⚠ **Do not over-tighten the T-port® Top**

⚠ **Use external connection tube affixed with skin-friendly tape**

⚠ **T-port® Access should only be used with the supplied Enteral Catheter**

⚠ **Avoid oblique position and positioning in a skin-fold**

⚠ **The Enteral Catheter can dislocate up into the stomach or even out into the peritoneum if the T-fastener is too loosely affixed**

- Treatment can be initiated at this time by connecting the external device to the connection tube leading to the ENFit or Luer-Lock connector on the T-port®.

Postoperative care

- Four hours bed rest, followed by careful mobilisation.
- Bleeding control.
- Suitable pain relief.
- Check haemoglobin.
- Fasting for 6 hours, and then the patient can carefully start to drink water, up to 500 ml until the next day. If no pain or other problems, solid food per os can be given. Pain could be a sign of leakage, and intake of fluids or solid food should then be stopped and a doctor contacted.
- Change the bandage if there are signs of bleeding through the dressing. Keep the bandage dry. Trained nursing staff should change the bandage under sterile conditions.
- Avoid rotation or angled force on the T-port® during healing.
- If necessary, check the position of the T-port® Enteral Catheter with a plain x-ray of the abdomen.
- Cutting of skin sutures and T-fastener line is done after 2-3 weeks, and the wound can then be left open if there are no signs of infection. The patient can then shower with the T-port®. After 1 month, there should be no need for any bandage.
- The patient should be told to avoid any traction or rotation force on the T-port®, especially during the first month of healing.
- If there is any sign of infection: take culture, give antibiotics and treat the wound regularly.

Care after healing period

- Avoid traction or rotation of the T-port®.
- Keep the area around the port clean and dry. Clean around the T-port® with soap and water, 1-2 times every day. Preferably do this with a shower head and using wet cotton buds. The brownish material produced around the port is cell debris from the skin edges, and should be removed every day to prevent infection.
- It is not unusual for there to be a cyclic recurrent slight redness of the skin edges around the T-port®, which will usually need no further treatment other than daily cleaning. More pronounced cases can be treated with saline solution, and by covering the skin with suitable protective materials, such as Skin-X (ErgoNordic, Sweden) or Duoderm (ConvaTec, USA).
- If there are signs of more pronounced redness, secretion and hypergranulation tissue around the T-port®, use the same hygiene principals as above and apply cortisone ointment grade 3 two times a day for 14 days, which should then be gradually reduced. If superficial bacterial infection is suspected, this can be combined with local antibiotics. Silver nitrate (lapis) 2 times a week can be used as an alternative for treatment of the hypergranulation tissue – ensure careful use in accordance with institutional guidelines, as this can cause erosion of the skin.
- In the event of severe redness, signs of pus and general effects, a bacterial culture should be taken. Wash with chlorhexidine solution and cover with a sterile dressing once a day. Per oral antibiotics should be considered and chosen in accordance with the culture results. If infection cannot be controlled, the T-port® can be explanted and the wound sutured under local anaesthetic. After 1 month of healing, a re-implantation of T-port® Enteral Access System can be performed.

Exchange of the T-port® Enteral Catheter

- The T-port® Enteral Catheter (4) is exposed to long-term mechanical stress. An exchange is recommended every third year.
- T-port® Enteral Catheter exchange involves a risk of infection and should be performed in accordance with careful aseptic rules, with disinfection of the wound around the skin by a specially trained doctor. It is recommended to give prophylactic antibiotics 2 days before and 5 days after the exchange of the catheter.
- Use the T-port® Top Wrench (7) and the Base Holder (6) to remove the T-port® Top (2). Screw the T-port® Catheter Holder into the T-port® Catheter Cone (3) at the end of the T-port® Enteral Catheter (4), and pull out over a stiff guide wire. Replace with a new T-port® Enteral Catheter (4). Make sure that the tip is placed beyond the ligament of Treitz.
- Screw a new T-port® Top (2) onto the T-port® Base (1). Tightening the T-port® Top (2) to the level where the Top's lower surface comes close to the upper surface of the T-port® Base (1) is enough to create a tight seal. This occurs at a torque of around 0.8 Nm and with a gap of 0.5 mm. Additional torque will not improve the tightness.

⚠ **Do not re-use the T-port® Top (2)**

⚠ **Be careful to avoid traction or rotation force on the T-port® Base (1). Use the Base Holder (6).**

⚠ **Do not over-tighten the T-port® Top (2)**

Explantation of the T-port®

- Explantation should be performed under careful aseptic rules, with disinfection of the wound around the skin by a specially trained doctor. The area around the T-port® Base is infiltrated with local anaesthetics. If possible, unscrew the T-port® Top (2) and remove the T-port® Enteral Catheter (4) according to the instructions in Exchange of the T-port® Enteral Catheter and T-port® Top. Cut around the T-port® Base (1) and dissect beneath the flange. This usually has to be done with sharp scissors and/or a knife. If the catheter has not been removed, it could be accidentally cut, which should be avoided. After the system is removed, the skin can usually be closed with sutures. If the healing process is uneventful, a re-implantation can be performed after 1 month.

Explantation and implantation of new T-port® on the same occasion

- Any sign of infection should be treated before the procedure, with local aseptic cleaning and antibiotics. It is recommended to give antibiotics for at least 2 days before and 5 days after the procedure. Remove the T-port® as described above, but place a stiff guide wire through the tube before it is removed. Remove inflammatory and excessive scar tissue. Flush the wound with saline solution, and be meticulous with regard to haemostasis.
  Implant a new T-port® and affix it well with 3 to 4 fascia sutures, as described above. There is no need for T-fasteners, as the catheter is inserted through the old healed fistula. Suture the skin, and leave no gap between the skin edge and the tower. The bandage should be applied with compression of the wound, in order to minimise risk of bleeding.

12. INFORMATION AND INSTRUCTIONS FOR THE PATIENT

- Avoid traction, bending or rotation of the T-port®.
- Use the extension tube between the port and the pump. If possible, the extension tube should be affixed with a skin-friendly tape to avoid movements of the port.
- Keep the area around the port clean and dry.
- Clean around the T-port® with soap and water, 1-2 times every day. Preferably do this with a shower head and use wet cotton buds (see illustration 23-26).
- The brownish wax-like material produced around the port is cell debris from the skin edges and should be removed every day to prevent infection. Pay special attention to the sinus around the port.
- Make sure that there is no leakage of medication at the couplings.
- Flush the tube with cold or tepid drinking water after use (20-40 ml).

⚠ **Improper cleaning increases the risk of discharge and low-grade inflammation, which, in turn, may lead to pocket infection**

13. REPORTING INCIDENTS

Any serious incident that may occur in relation to the device should be reported to Transcutan AB and the competent authority of the Member State in which the user and/or patient is established.

14. MRI SAFETY INFORMATION

The Transcutan T-port® contains stainless steel in the T-port® Top and the T-port® Catheter Cone, as well as titanium in the T-port® Base. The Top is located outside the body, and the Catheter Cone is affixed inside the base with no contact with tissue. The T-port® Base is well-affixed with sutures and healed into the subcutaneous tissue.

Non-clinical testing has demonstrated that the T-port® is MR Conditional, with the following results:

Displacement force and torque effects

The tested port showed that magnetic displacement forces rescaled to a field gradient of 15T/m (1500G/cm) are twice as large as the gravitational force. In a field of 30T/m, it is four times larger. The forces in a field gradient of 15T/m will not be a risk for the patient. If even a field gradient of 30T/m (four times the gravitational force) would be acceptable, which can only be judged with further data on the fixation of the port.

Deflection angles in a main magnetic field gradient of a 3T scanner with a field gradient of 15T/m (1500G/cm) were ≤64±1° for the implants tested. The magnetic displacement force was ≤0.33±0.02N.

The magnetic torque effects measured by the pully methods were at least 3x lower than the gravitational torque and do not pose any safety risk.

RF heating effects

RF heating tests of the button showed RF heating of up to 6.5°C (at 1.5T) and 4.7°C (at 3T) for a wbSAR of 4W/kg. The RF heating of 6.5°C will result in a CEM43 value of 7.1 min, which is below the limit of 15 min. No cooling effects from blood flow and perfusion have been considered.

Imaging artifacts

The tested implant (T-port® Enteral Access System) showed artifacts up to 55 mm from the implant surface (spin echo sequence ≤55 mm) for the metallic parts, and up to 1 mm for the tube. The lumen on the tube was clearly visible.

These artifact sizes are for the MR sequences requested in the ASTM standard. It is likely that clinical MR protocols may show smaller artifacts.

Note: The T-port® Enteral Access System was tested in a 1.5T and a 3T system. Force and torque tests are valid for ≤3_T_. RF heating is only valid for the tested field.

The full report is available on request.

15. IMPLANT CARD

The T-port® Enteral Access System is supplied with an Implant Card, which should be completed according to the accompanying instructions and given to the patient after implantation.

The patient should be informed regarding the information on the Implant Card and its purpose, e.g.:

- Enable the patient to identify the implanted device, and to gain access to other information related to the implanted device.
- Enable the patient to identify themselves as a person requiring special care in relevant situations, e.g. security checks.
- Enabling e.g. emergency clinical staff or first responders to be informed about special care/needs for relevant patients in case of emergency situations.

16. ILLUSTRATIONS

1. Avoid placing the port in a skin-fold.
2. Avoid placing the T-port® Base near the costal arch.
3. Nasogastric tube for insufflation of air.
4. Sterile wash of abdomen.
5. Marking of implantation site.
6. Local anaesthesia.
7. Anchor needle. Confirm its position inside the stomach by injection of iodine contrast and/or aspiration of air bubbles into the syringe.
8. Insert the guide wire.
9. Placing anchors for fixation of stomach. Affix the first anchor with forceps, and place the others with at least 2 cm distance from the implantation site.
10. Place a 4-5 Fr catheter beyond the ligamentum of Treitz.
11. Under local anaesthesia, make incision with dissection of the subcutaneous pocket.
12. Muscle fascia sutures for fixation of port and meticulous haemostasis.
13. Withdraw the catheter over a guide wire, and dilate (10-12 Fr) the puncture hole.
14. Mount the T-port® Base on the T-port® Enteral Catheter, and insert it over the guide wire.
15. Cut the central anchor thread, and withdraw the guide wire.
16. Screw the T-port® Top with plug until there is a small gap (around 0.5 mm) between the T-port® Top and T-port® Base. Thread the fascia sutures through the slits of the flange.
17. Affix the T-port® Base in the pocket with the fascia sutures, and avoid oblique positioning.
18. Flush the pocket with saline solution and suture the skin. Ensure it is sutured tightly against the neck of the port.
19. Connect the extension tube. Check for leakage and the position of catheter by flushing the system with iodine contrast or air.
20. Affix the extension tube with skin-friendly tape, and apply a bandage with some compression over the wound site.
21. After 2 to 3 weeks, the skin sutures and the anchor threads should be cut.
22. Implanted T-port® with Catheter.
23. Clean with soap and water.
24. Remove the debris using (for example) cotton buds or a compress.
25. Wet/flush with water to clean the area.
26. Dry carefully.
27. Connection and disconnection of external tube (for medication or nutrition).

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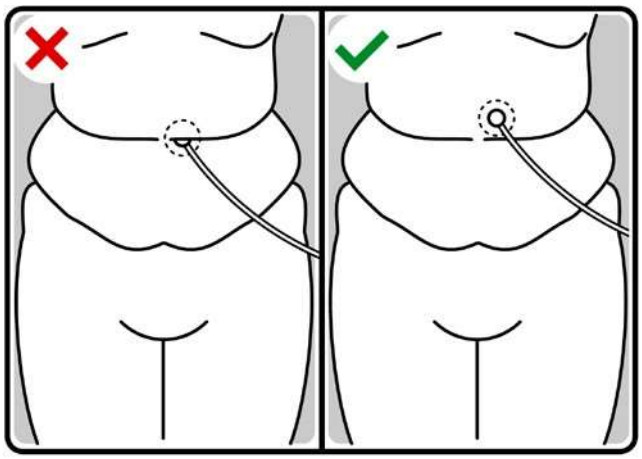

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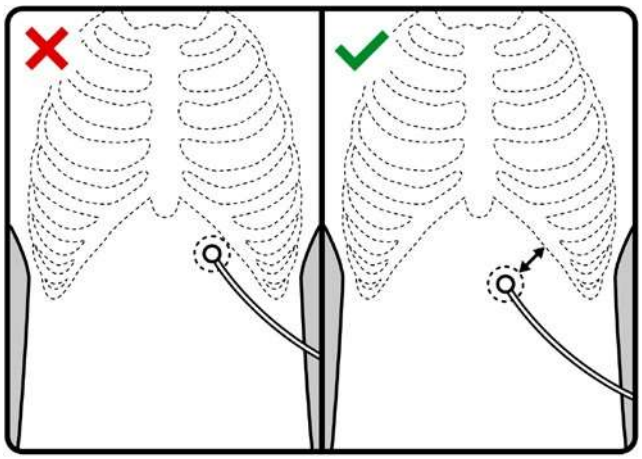

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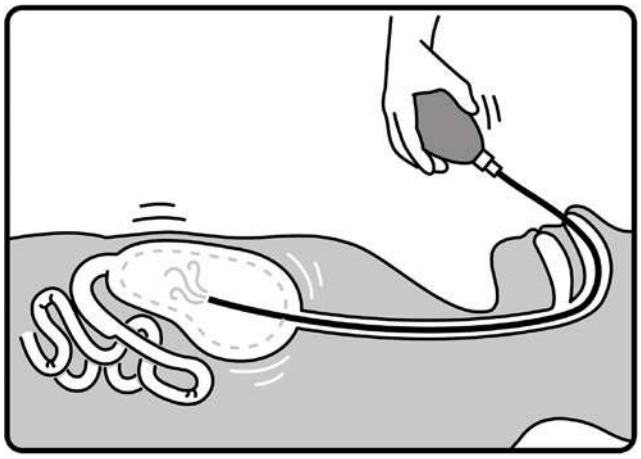

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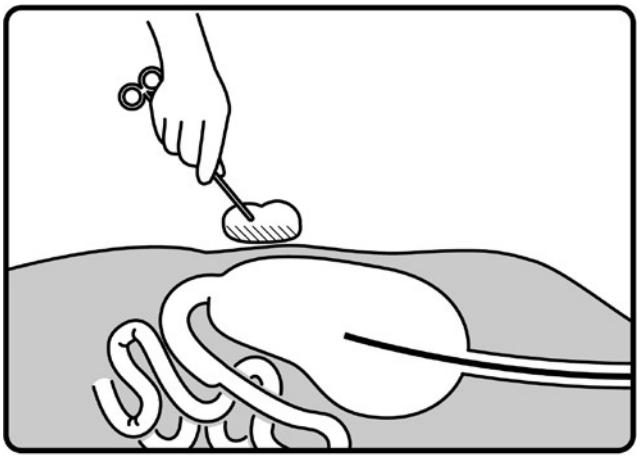

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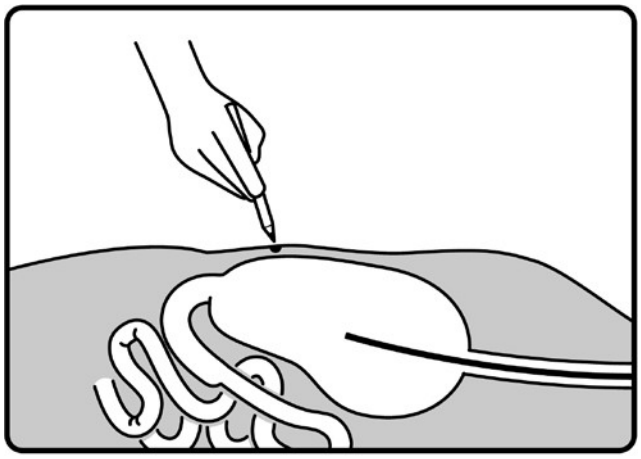

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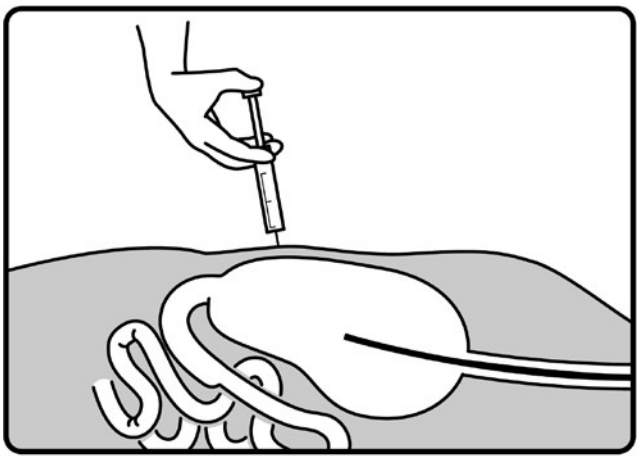

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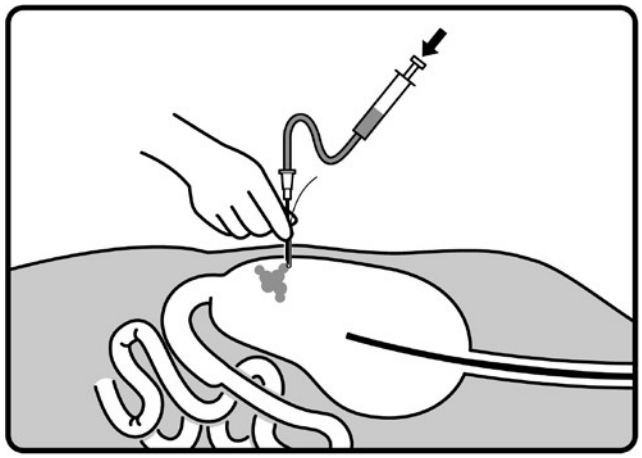

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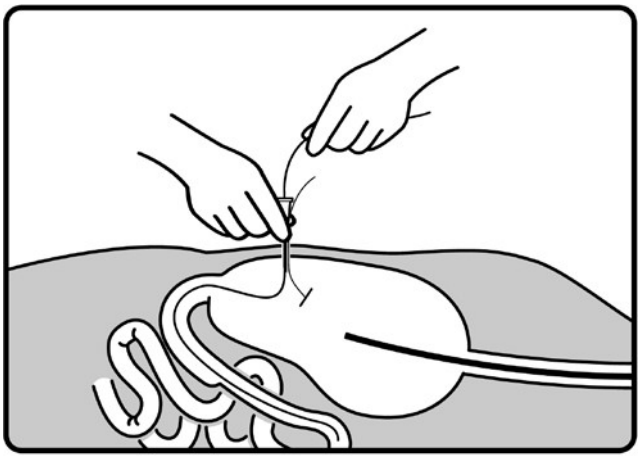

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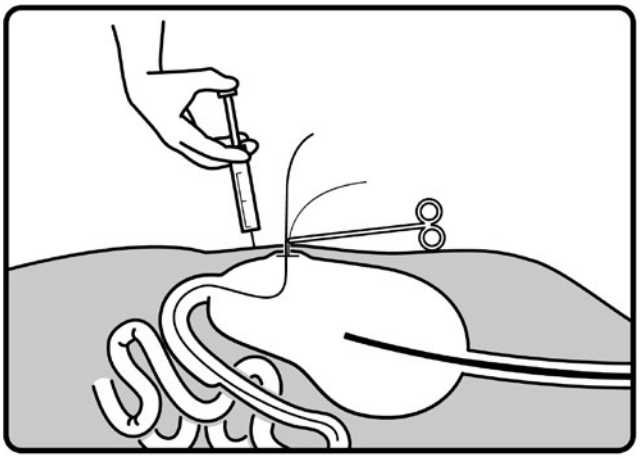

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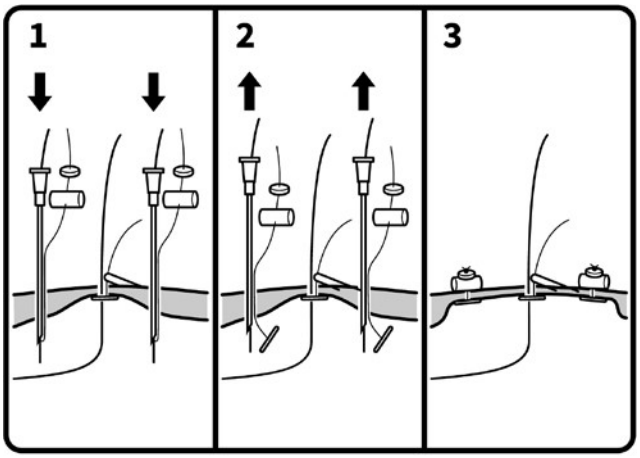

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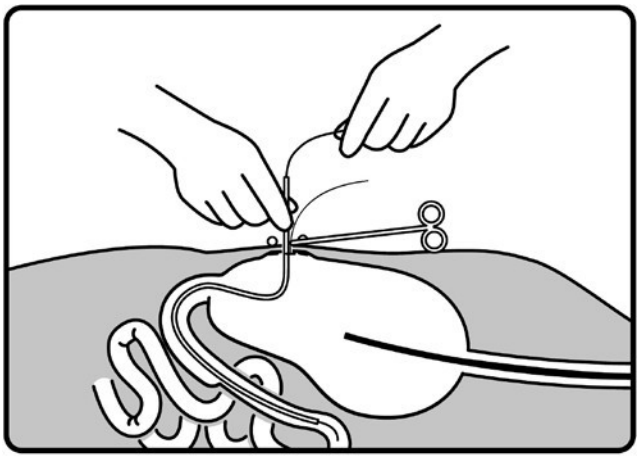

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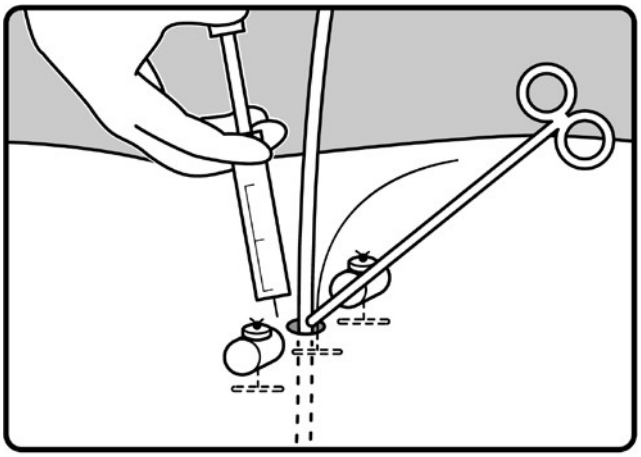

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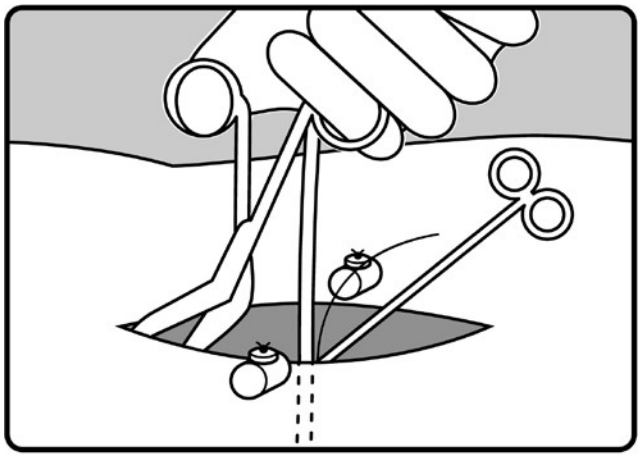

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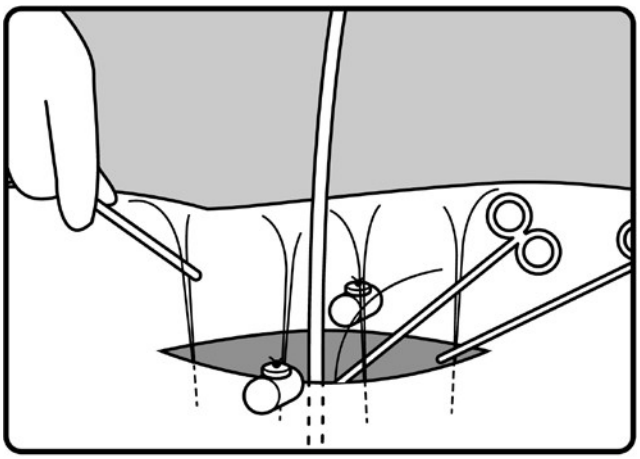

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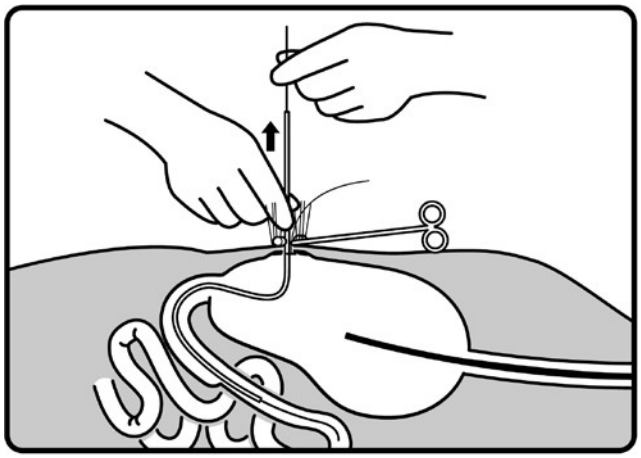

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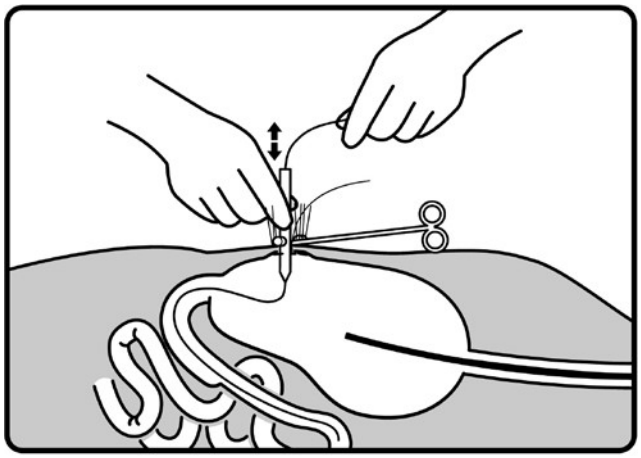

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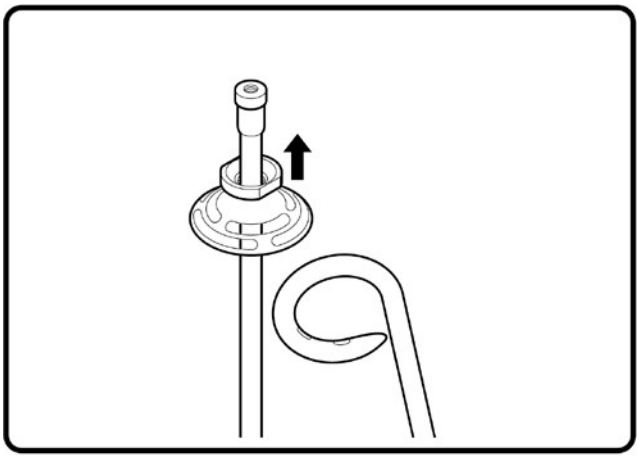

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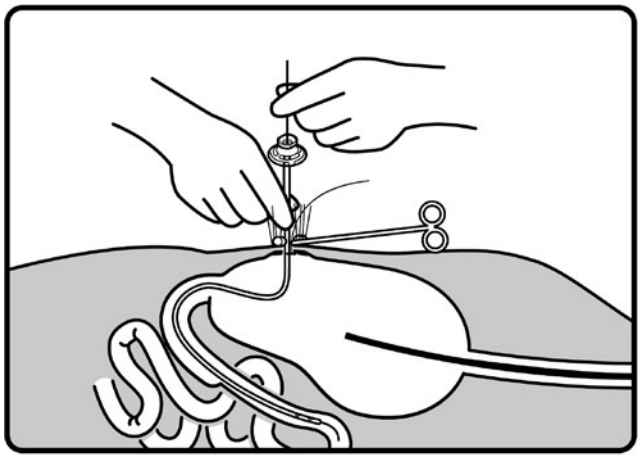

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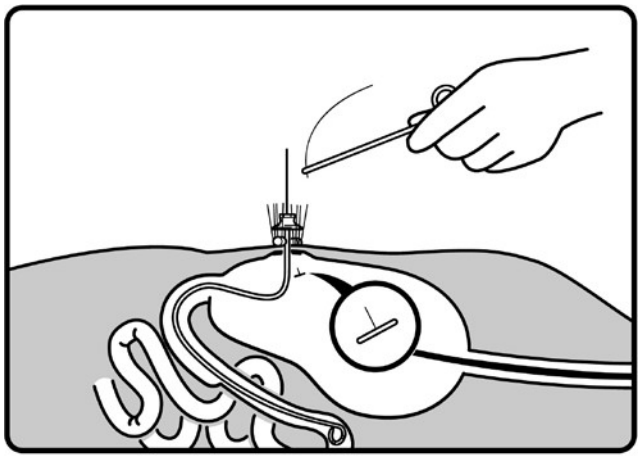

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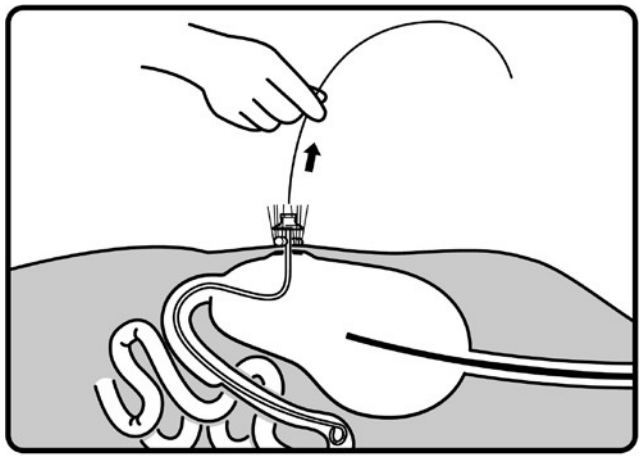

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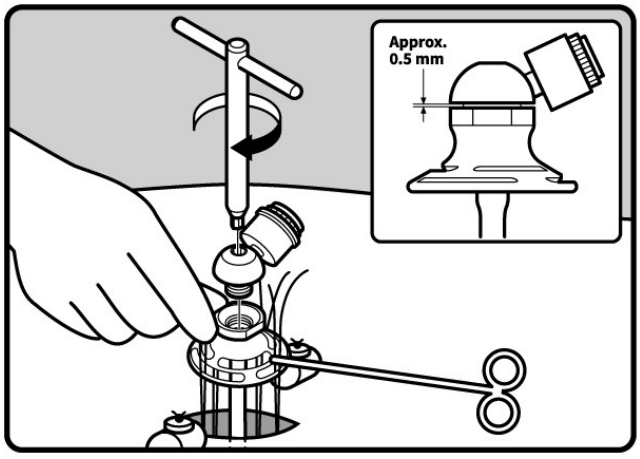

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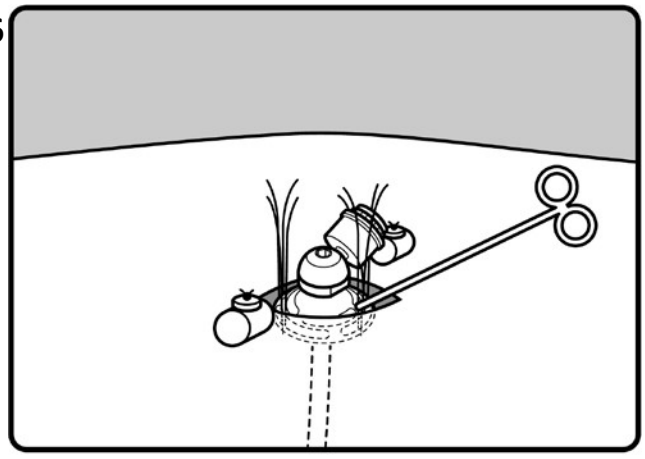

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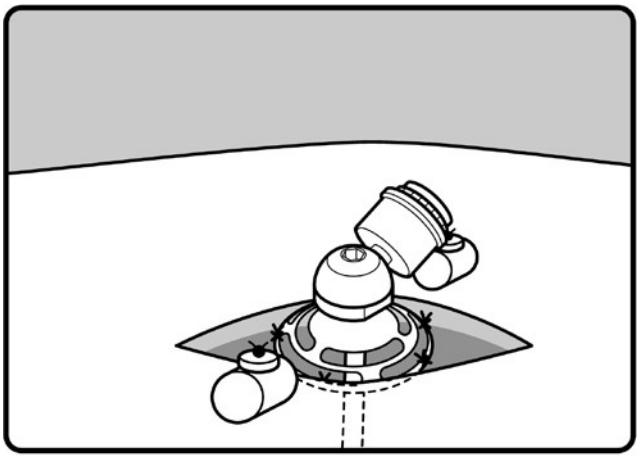

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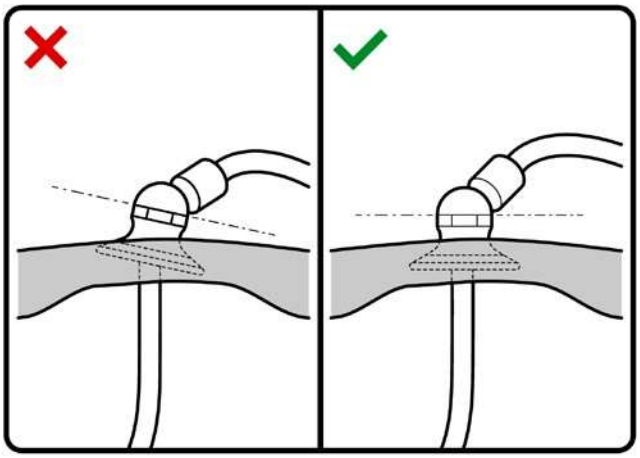

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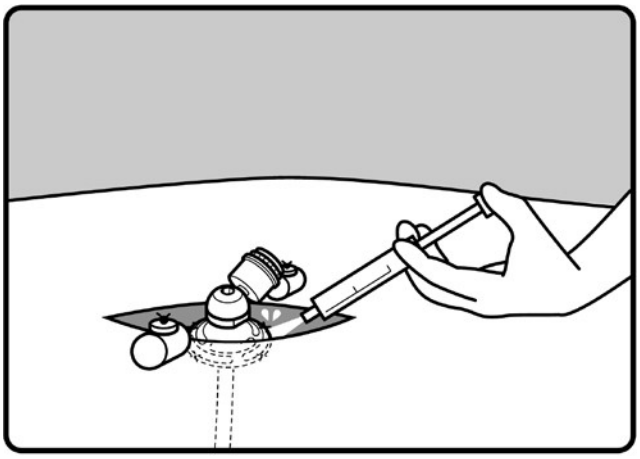

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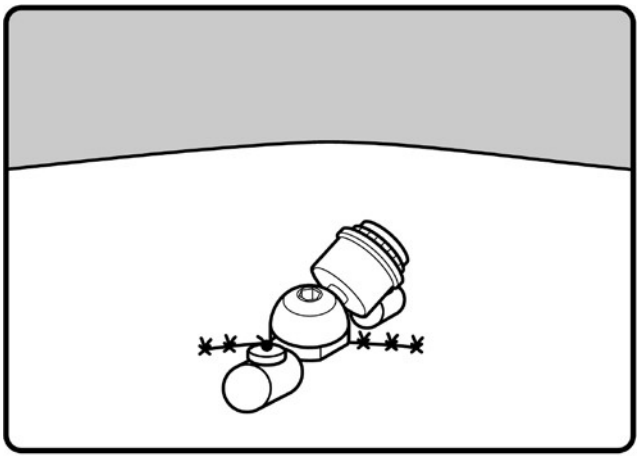

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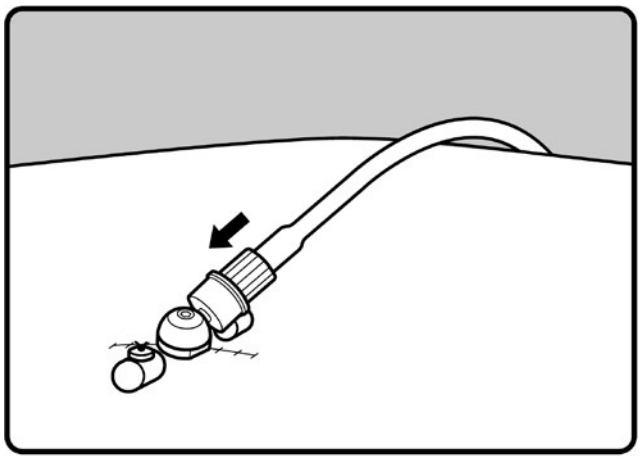

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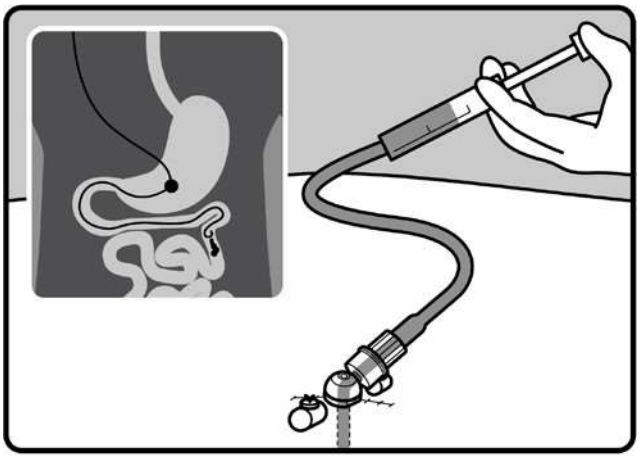

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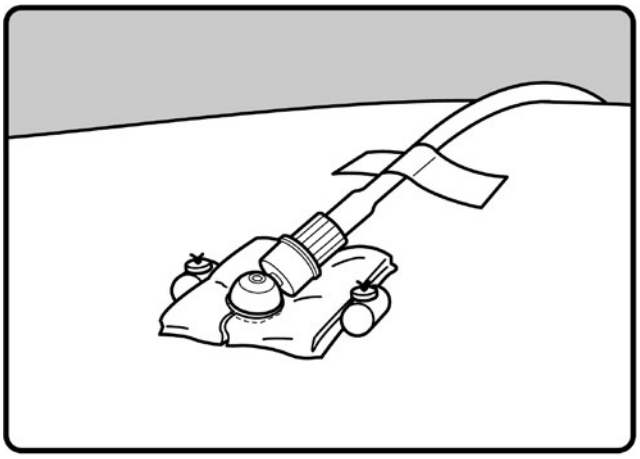

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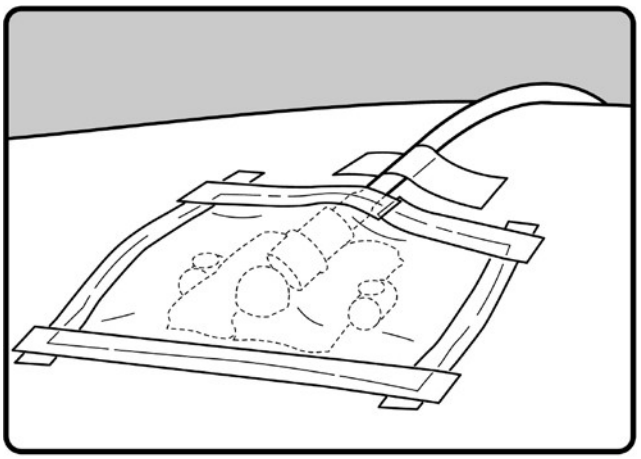

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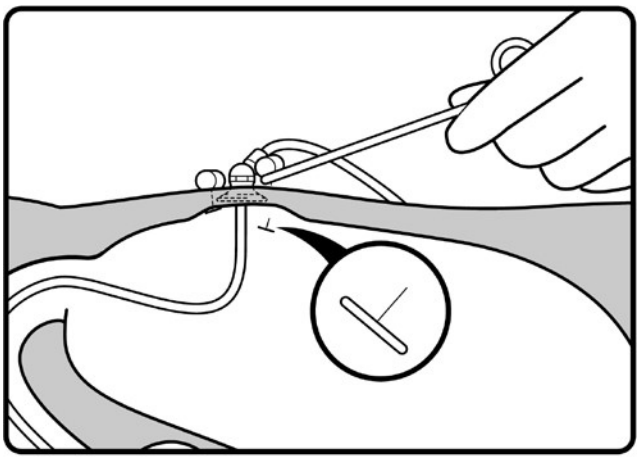

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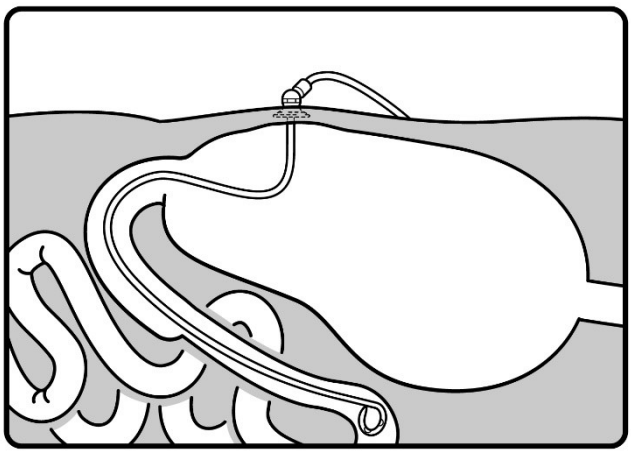
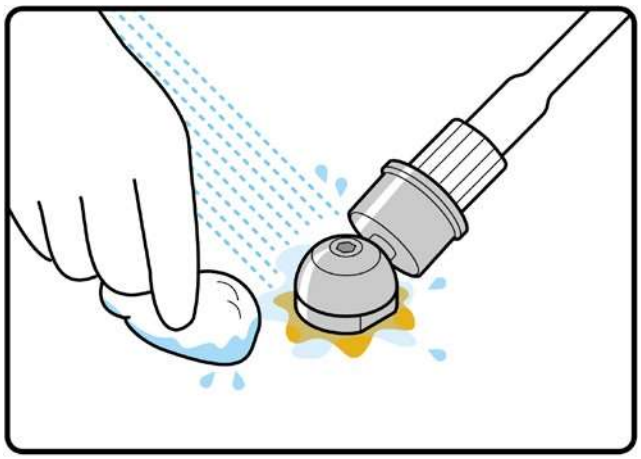


Wash and clean

23



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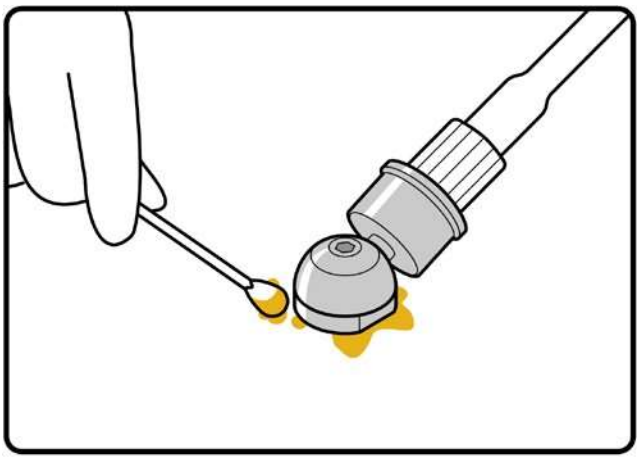

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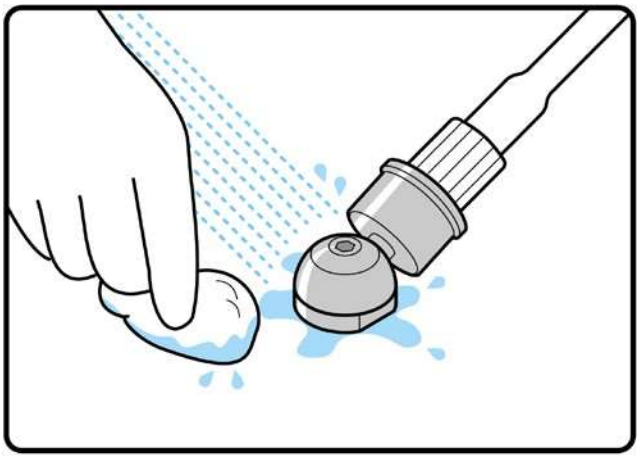

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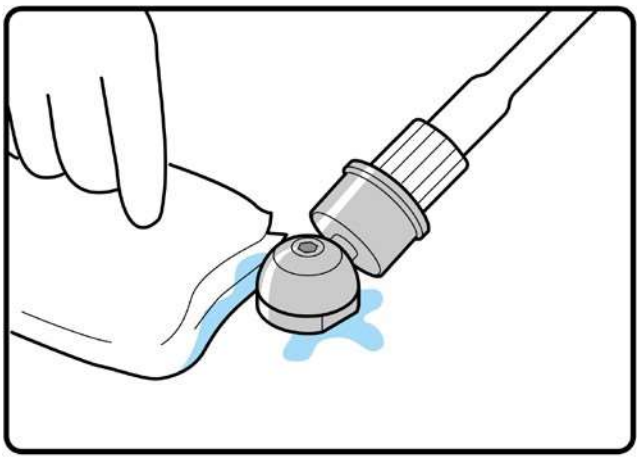

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